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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 07/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/023,437	JOHNSTON ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-27,29-39,41-45,50-61,74,76-81,83 and 92-115* is/are pending in the application.

4a) Of the above claim(s) *26,27,29-38,50-61 and 76-81* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25,39,41-45,74, 83 and 92-115* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This action is responsive to Applicant's amendment and response filed May 16, 2006. Claims 1-24, 28, 40, 46-49, 62-73, 75, 82 and 84-91 have been cancelled. Claims 26-27, 29-38, 50-61 and 76-81 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

2. The text of those sections of the Title 35, U.S. code not included in this action can be found in the prior Office Action.

Rejection Maintained

3. The rejection under 35 U.S.C. 112, first paragraph is maintained for 92 and 96-99 for the reasons set forth on pages 2-7, paragraph 4 of the Final Office Action.

The rejection was on the grounds that the claims while being enabling for a method of immunizing an animal comprising providing to the animal; at least one *Chlamydia* antigen corresponding to SEQ ID No. 9 or SEQ ID No. 7 and further comprising a second *Chlamydia* antigen corresponding to SEQ ID No. 11 or SEQ ID No. 13 does not reasonably provide enablement for variants of the SEQ ID Nos. 7, 9, 11 or 13 encompassed by the claims that can be used in the claimed method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification has failed to provide a structure for variants encompassed by the claimed invention.

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of proteins broadly encompassed by the claims and the claims broadly encompass a significant number of inoperative species. Since the amino acid sequence of the protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and still retain similar activity requires a knowledge with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expected intolerant to modification) and detailed knowledge of the ways in which the protein's structure relates to function. However, the problem of

the prediction of protein's structure from mere sequence data of a single protein and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein and finally what changes can be tolerated with respect thereto is extremely complex and outside of the realm of routine experimentation.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen multiple substitutions or multiple modifications of other types and the positions within the protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining similar activity are limited in any polynucleotide and the result of such modifications is unpredictable based on the instant disclosure. One skilled in the art would expect any tolerance to modifications. The sequence of some proteins is highly conserved and one skilled in the art would not expect tolerance to any amino acid modification in such protein.

Thomas E. Creighton, in his book, *"Proteins: Structures and Molecular Properties, 1984"*, (page 315) teaches that variation of the primary structure of a protein can result in an instable molecule. He teaches that a single amino acid change can cause a mutant hemoglobin to have lower stabilities due to any of several causes: 1) alteration of close-packing of the interior; loss of one group that normally participates in a hydrogen bond or salt bridge; 2) the introduction of a charged or polar group into the interior or the insertion into a helical region of a proline residue, which must distort the alpha-helix; 3) while sometimes radical changes of surface groups, even introduction of a non-polar side chain- have no great effect on stability.

Thomas E. Creighton, in his book *"Protein Structure: A Practical Approach, 1989; pages 184-186"* teaches that present day site directed mutagenesis of a gene allows any amino acids in a protein sequence to be changed to any other, as well as introducing deletions and insertions". The reference goes on to teach that it is difficult to know which amino acid to change and which is the best residue to substitute for the desired functional and structural effect.

Nosoh, Y. et al in *"Protein Stability and Stabilization through Protein Engineering, 1991"* (chapter 7, page 197, second paragraph) adds support to Thomas E. Creighton, by teaching that results so far accumulated on the stability and stabilization of proteins appear to indicate that the strategy for stabilizing proteins differ from protein to protein and that any generalized mechanisms for protein stability have not yet been presented.

Factors to be considered in determining whether undue experimentation is required are set forth in In re Wands 8 USPQ2d 1400. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Applying the above test to the facts of record, it is determined that 1) no declaration under 37 C.F.R. 1.132 or other relevant evidence has been made of record establishing the amount of experimentation necessary, 2) insufficient direction or guidance is presented in the specification with respect to selecting other proteins having claimed functional features, 3) the relative skill of those in the art is commonly recognized as quite high (post-doctoral level). One of skill in the art would require

guidance, in order to make or use proteins all variants of SEQ ID Nos. SEQ ID Nos. 7, 9, 11 or 13 in manner reasonable in correlation with the scope of the claims. Without proper guidance, the experimentation is undue.

The Applicant has not provided sufficient guidance to enable one of skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of deletions or substitutions and fragments of any size. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970). Without such guidance, the changes which can be made in the amino acid's structure and still maintain activity is unpredictable and the experimentation left those skilled in the art is unnecessarily and improperly, extensive and undue. See Amgen Inc v Chugai Pharmaceutical Co Ltd. 927 F 2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991) at 18 USPQ2d 1026-1027 and Exparte Forman, 230 U.S. P.Q. 546(Bd. Pat=. App & int. 1986).

Applicant's Arguments

A) Applicant urges that the antigens of the invention are limited to nine amino acid fragments of the SEQ ID Nos. 7, 9, 11 and 13 and induce a protective immune response against *Chlamydia psittaci.* Applicant urges that the antigens that do not meet these requirements are not within the scope of the claims.

Applicant refers to Janeway , Jr. 2001 to support their position.

B) Applicant urges that the instant specification has working examples. Applicant urges that the instant specification demonstrates that the 443 amino acid polypeptide of SEQ ID NO:9 and the 100 amino acid polypeptide of SEQ ID NO:13 can be used to immunize an animal. Applicant urges that 9-28mer polypeptides of the claimed protective protein may induce protective immunity in different individuals. Applicant urges that the identification of the protective genes is described on pages 64-80 in Examples 1-6 of the instant specification. Applicant urges that one skilled in the art would simply make and use these at least nine-amino acid antigen and antigenic

fragments that are taught by the specification. Applicant urges that it would be not require undue experimentation for one of skill in the art to make and use fragments and variants of SEQ ID Nos.7, 9, 11 and 13 based on the instant disclosure.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed May 16, 2006 have been fully considered but they are not persuasive.

A) It is the Examiner's position that the claims are not limited to polypeptides that comprise SEQ ID NO:7, 9, 11 or 13. It should be noted that the functional language recited in the claims would allow the skilled artisan to obtain fragments of SEQ ID Nos:7, 9, 11 and 13 that have the recited function. However, there is no guidance in the instant specification regarding the selection of variants encompassed by the claimed invention. The Examiner recognizes the state of the art regarding finding "epitopes" within a protein and thus the Examiner recognizes the teachings pointed out by Janeway, Jr.

B) The claims as amended read on sequences that are less than the full-length of SEQ ID Nos. 7, 9, 11 and 13 (e.g. fragments of SEQ ID NOs: 7, 9, 11 and 13) and also read on sequences that are variants of SEQ ID NO:7, 9, 11 and 13. The instant specification is not enabled for methods of immunizing animals comprising the administration of variants of SEQ ID NOs: 7, 9, 11 and 13. It should be remembered that the statute under 35 U.S.C. 112, first paragraph requires that the specification teach how to make and use polypeptides of the claimed invention not how to "find"

variants of the *Chlamydia* polypeptides (e.g. SEQ ID NOs. 7, 9, 11 and 13) used in the claimed method. A structure is required for the polypeptides used in the claimed method. It should be remembered that while recombinant and mutagenesis techniques are known, it is not routine in the art to screen multiple substitutions or multiple modifications of other types and the positions within the polypeptide's sequence. Amino acid modifications can be made with a reasonable expectation of success in obtaining similar activity are limited in any polypeptide and the result of such modifications is unpredictable based on the instant disclosure.

While independent claim 92 is directed to a method of immunizing an animal comprising administering *Chlamydia psittaci* antigen comprising the amino acid sequence as set forth in SEQ ID NO.9, dependent claims are directed to variants of SEQ NOs: 7, 9, 11 and 13 and these variants are not enabled by the instant disclosure. Applicant has not shown how to "make and use" variants of SEQ ID NOs:7, 9, 11 and 13. Therefore, Applicant has not met their burden as set forth in 35 U.S.C. 112, first paragraph.

It should be noted that the claims are not limited to a polypeptides that comprise SEQ ID NO:7, 9, 11 or 13. Claims read on variants of SEQ ID NOs:7, 9, 11 and 13. Therefore, the following art rejections are maintained.

4. The rejection under 35 U.S.C. 102(e) is maintained for 25, 39, 41-45, 74 and 83 for the reasons set forth on pages 8-9, paragraph 6 of the Final Office Action.

The rejection was on the grounds that Griffais et al teach a method of immunizing an animal comprising administering vaccine compositions comprising at least one *Chlamydia* antigen or antigenic fragment in an amount to induce an immune response (columns 62-64). Graffais et al teach that the vaccine composition are administered to a mammalian host (column 62) including humans (column 63). Griffais et al teach that any number of antigens may be included in the invention (see Table 1). Griffais et al teach that antigen from *Chlamydia psittaci* may be included in the invention. Therefore, the prior art meets the claim limitation "...wherein the method is effective to induce an immune response against *Chlamydia psittaci*". The prior art teaches antigenic fragments of SEQ ID Nos. 7 and 9 (corresponding to the first *Chlamydia* antigen) as well as antigenic fragments of SEQ ID Nos. 13 (corresponding to the second *Chlamydia* antigen). SEQ ID NO: 59 of the prior art corresponds to fragments of SEQ ID NOs: 7 and 9. SEQ ID NO: 12 of the prior art corresponds to antigenic fragments of SEQ ID, NO:13. See the attached sequence alignments.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant's Arguments

A) Applicant urges that Applicant as figured out which of the approximately 1,050 *Chlamydia psittaci* proteins work as immunogens which requires identifying sequences that generate protective immune response. Applicant states that "Applicants have identified the gene product *Chlamydia* cannot "hide" from the immune response of the infected individual despite the fact that these gene products elicit an immune response that is unfavorable for the chlamydia bacteria because they allow the host to eliminate *Chlamydia*" (page 22 of Applicant's remarks).

B) Applicant urges that Griffais et al do not provide vaccines or useful teachings as how to obtain them. Graffais et al provide no more than standard vaccine methodology. Applicant urges that the claimed variants and fragments of the present

invention are not disclosed in Graffais et al. Applicant urges that Graffais et al only has claims to polynucleotides comprising certain open reading frames (ORFs) from the *Chlamydia pneumoniae* genome and methods for expressing a protein from such ORFs. Applicant urges that there are no claims to vaccines or the use of ORFs in making vaccines, let alone specific guidance concerning antigenic fragments of SEQ ID Nos. 7, 9, 11 and 13.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed May 16, 2006 have been fully considered but they are not persuasive.

A) To address Applicant's comment regarding the protein of the prior art being immunogenic, it should be noted that Graffais et al teach that the polypeptides, proteins or fusion proteins be used as immunogens to generate antibodies or other derivatives or analogs thereof (column 54). It should be noted that Graffais et al teach that the polypeptides of the invention can be used in pharmaceutical compositions, immunogenic compositions and vaccine compositions (columns 61-62). It should be further noted that Graffais et al teach the administration of the polypeptides of the invention to animals to elicit immune responses (columns 63-64).

To address Applicant's comments regarding gene products that elicit an immune response that is unfavorable for the chlamydia bacteria, it is unclear as to what Applicant is intends by this comment. The Examiner asks that Applicant clarify this statement in the response to this Office action.

B) The pending claims are directed to a method of immunizing an animal comprising preparing and administering *Chlamydia psittaci* antigen "having a sequence of either SEQ ID NOs:7, 9, 11 or 13". It should be noted that "having or comprising" is open-claim language. See MPEP 2111. The claims are not limited to the polypeptides set forth in SEQ ID NO:7, 9, 11 or 13. These claims read on sequences that are less than the full-length of SEQ ID Nos. 7, 9, 11 and 13 (e.g. fragments of SEQ ID NOs: 7, 9, 11 and 13) as well as variants of SEQ ID Nos. 7, 9, 11 and 13. Graffais et al disclose amino acid sequences that are fragments. The prior art teach that SEQ ID NO: 59 of the prior art corresponds to fragments of SEQ ID NOs: 7 and 9 which are at least nine amino acids of SEQ ID No: 7 or 9. SEQ ID NO: 12 of the prior art corresponds to fragments of SEQ ID NOs:11 and 13 which are at least nine amino acids of SEQ ID No: 11 or 13. Applicant has provided no side-by-side comparison to show that the method of the prior art is not the same as the claimed method.

To address Applicant's comments regarding, Graffais et al and claimed subject matter contained in the document, it should be noted that the entire document is relied upon as a prior art reference and not just the subject matter specifically recited in the claims of the issued patent.

There is nothing of record to suggests that the method of the prior art differs from that of the claimed invention. Thus, Graffais et al anticipate the claimed invention.

5. The rejection under 35 U.S.C. 102(b), is maintained for 25, 39, 41-45, 74, 83 for the reasons set forth on pages 10-11, paragraph 7 of the Final Office Action.

The rejection was on the grounds that Griffais teaches a method of immunizing an animal comprising administering vaccine compositions comprising at least one *Chlamydia* antigen or antigenic fragment in an amount to induce an immune response (page 71-73). Graffais teaches that the vaccine composition are administered to a mammalian host including humans (pages 72-73). Griffais teaches that any number of antigens may be included in the invention (see Table 1). Griffais teaches that antigen from *Chlamydia psittaci* may be included in the invention. Therefore, the prior art meets the claim limitation "...wherein the method is effective to induce an immune response against *Chlamydia psittaci*". The prior art teaches antigenic fragments of SEQ ID Nos. 7 and 9 (corresponding to the first *Chlamydia* antigen) as well as antigenic fragments of SEQ ID Nos. 13 (corresponding to the second *Chlamydia* antigen). SEQ ID NO: 59 of the prior art correspond to fragments of SEQ ID NOs: 7 and 9. SEQ ID NO: 12 of the prior art correspond to fragments of SEQ ID NO:13. See the attached sequence alignments.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant's Arguments

A) Applicant urges that Applicant as figured out which of the approximately 1,050 *Chlamydia psittaci* proteins work as immunogens which requires identifying sequences that generate protective immune response. Applicant states that "Applicants have identified the gene product *Chlamydia* cannot "hide" from the immune response of the infected individual despite the fact that these gene products elicit an immune response that is unfavorable for the *Chlamydia* bacteria because they allow the host to eliminate *Chlamydia* (page 22 of Applicant's remarks).

B) Applicant urges that Griffais et al do not provide vaccines or useful teachings as how to obtain them. Graffais et al provide no more than standard vaccine methodology. Applicant urges that the claimed variants and fragments of the present

invention are not disclosed in Graffais et al. Applicant urges that Graffais et al only has claims to polynucleotides comprising certain open reading frames (ORFs) from the *Chlamydia pneumoniae* genome and methods for expressing a protein from such ORFs. Applicant urges that there are no claims to vaccines or the use of ORFs in making vaccines, let alone specific guidance concerning antigenic fragments of SEQ ID Nos. 7, 9, 11 and 13.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed May 16, 2006 have been fully considered but they are not persuasive.

A) To address Applicant's comment regarding the protein of the prior art being immunogenic, it should be noted that Graffais et al teach that the polypeptides, proteins or fusion proteins may be used as immunogens to generate antibodies or other derivatives or analogs thereof (page 70). It should be noted that Graffais et al teach that the polypeptides of the invention can be used in pharmaceutical compositions, immunogenic compositions and vaccine compositions (pages 72-73). It should be further noted that Graffais et al teach the administration of the polypeptides of the invention to animals to elicit immune responses (see the Abstract and pages 70-71).

To address Applicant's comments regarding gene products that elicit an immune response that is unfavorable for the chlamydia bacteria, it is unclear as to what Applicant is intends by this comment. The Examiner ask that Applicant clarify this statement in the response to this Office action.

B) The claims are directed to a method of immunizing an animal comprising preparing and administering *Chlamydia psittaci* antigen "having a sequence of either SEQ ID NOs:7, 9, 11 or 13". It should be noted that "having or comprising" is open-claim language. See MPEP 2111. The claims are not limited to the polypeptides set forth in SEQ ID NO:7, 9, 11 or 13. These claims read on sequences that are less than the full-length of SEQ ID Nos. 7, 9, 11 and 13 (e.g. fragments of SEQ ID NOs: 7, 9, 11 and 13) as well as variants of SEQ ID Nos. 7, 9, 11 and 13. Graffais et al disclose amino acid sequences that are fragments. The prior art teach that SEQ ID NO: 59 of the prior art corresponds to fragments of SEQ ID NOs: 7 and 9 which are at least nine amino acids of SEQ ID No: 7 or 9. SEQ ID NO: 12 of the prior art corresponds to antigenic fragments of SEQ ID NOs:11 and 13 which are at least nine amino acids of SEQ ID No: 11 or 13. Applicant has provided no side-by-side comparison to show that the method of the prior art is not the same as the claimed method.

To address Applicant's comments regarding, Graffais et al and claimed subject matter contained in the document, it should be noted that the entire document is relied upon as a prior art reference and not just the subject matter recited in the claims of the document.

There is nothing of record to suggests that the method of the prior art differs from that of the claimed invention. Thus, Graffais et al anticipate the claimed invention.

New Grounds of Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 25, 39, 41-45, 74, 83 and 92-115 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a new matter rejection.* The amendment filed May 16, 2006 introduces new matter into the claims. The claims have been amended to recite, "... and accelerate elimination of the *Chlamydia psittaci* bacteria from an infected animal, (see lines 4-5 of claim 25). Dependent claims for example, claim 41, recite "wherein the second *Chlamydia psittaci* antigen has the effect of increasing the protective capacity against *Chlamydia psittaci*-induced disease and accelerates elimination of the *Chlamydia psittaci* bacteria from an infected animal". There is no support for this newly presented limitation in the instant specification. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. Applicant's amendment introduces "new matter" that is not supported by the original disclosure. The specification fails to show the newly recited limitation in the instant specification.

Applicant has failed to direct the Examiner as to where in the instant specification the support for this amendment is specifically shown or implied. The Examiner has reviewed the instant specification and has failed to find the support for the amendment. Applicant is required to cancel the new matter in the reply to this Office Action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 25 is rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 25 recites "...accelerates elimination...". How is this calculated or determined. Correction is required.

8. Claims 92, 94 and 95 is rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 92, 94 and 95 recite "...preparing a Chlamydia psittaci antigen ...". How is the antigen prepared? Does Applicant intend that the antigen is produced recombinantly or synthetically or isolated from an microorganism? Correction is required.

9. Claims 96, 100 and 107 are rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 96, 100 and 107 do not further limit claim 92 from

which it depends. In fact, it broadens the scope of claim 92. The dependent claims broadens the scope because they encompass a plurality of variants due to the recitation of "a variant of the amino acid sequence as set forth in SEQ ID NO:9. Correction is required.

10. Claims 97 and 101 are rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 97 and 101 do not further limit claim 93 from which it depends. In fact, it broadens the scope of claim 93. The dependent claims broadens the scope because they encompass a plurality of variants due to the recitation of "a variant of the amino acid sequence as set forth in SEQ ID NO:7. Correction is required.

11. Claims 98 and 102 are rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 98 and 102 do not further limit claim 94 from which it depends. In fact, it broadens the scope of claim 94. The dependent claims broadens the scope because they encompass a plurality of variants due to the recitation of "a variant of the amino acid sequence as set forth in SEQ ID Nos: 7, 11 and 13. Correction is required.

12. Claims 99 and 103 are rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 99 and 103 do not further limit claim 95 from which it depends.

In fact, it broadens the scope of claim 95. The dependent claims broadens the scope because they encompass a plurality of variants due to the recitation of "a variant of the amino acid sequence as set forth in SEQ ID NO:9. Correction is required.

13. Claims 92-115 are rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The preamble of claim 92 recites "a method of immunizing ...". Claim 92 also recites "...preparing a *Chlamydia* antigen..." . It is unclear as what Applicant intends by the step of preparing an antigen in a method of immunizing. Clarification and/or correction is required.

14. Claim 92 and 94 rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 92 recites the steps of preparing and administering a *Chlamydia psittaci* antigen. Claim 94, for example recites "wherein the method further comprises the steps of preparing and administering a second *Chlamydia psittaci*...". It is unclear as to when the first and second *Chlamydia psittaci* antigens are being administered. Are the two antigens administered together? Are the two antigens administered at the same time or are these two different compositions administered to the animal at separate administration steps? Further are these two Chlamydia psittaci antigen prepared according to the same method? Clarification and/or correction is required.

15. Claim 93 and 95 rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 93 recites the steps of preparing and administering a *Chlamydia psittaci* antigen. Claim 95, for example recites "wherein the method further comprises the steps of preparing and administering a second *Chlamydia psittaci*...". It is unclear as to when the first and second *Chlamydia psittaci* antigens are being administered. Are the two antigen administered together? Are the two antigens administered at the same time or are these two different compositions administered to the animal at separate administration steps? Further are these two Chlamydia psittaci antigen prepared according to the same method? Clarification and/or correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

16. Claims 25, 41-43, 74, 83, 92-106 and 113-115 are rejected under 35 U.S.C. 102(a) as anticipated by Kalenboeck et al *(FASEB Journal , April 2000, Vol. 14, No. 6, p. A1130, meetings held May 12-16, 2000)(Abstract).*

Claims 25, 41-43, 74, 83, 92-106 and 113-115 are drawn to a method of immunizing an animal comprising administering to the animal a *Chlamydia psittaci* antigen having a sequence of SEQ IS NO:7 in an amount effective to induce a protective immune response against *Chlamydia psittaci* wherein the immune response

protects against *Chlamydia psittaci*-induced disease and accelerates elimination of the Chlamydia psittaci bacteria from an infected animal and wherein the amount effective is at a nine amino acid fragment of the SEQ ID NO:7.

Kalenboeck et al teach a method of immunizing mice comprising administering to the animal a Chlamydia psittaci antigen. Kalenboeck et al teach that five of the clones conferred maximum protection from disease equal to or better than the best achievable protection mediated by prior low-level infection with live bacteria (see the Abstract). The amino acid sequences are inherent in the teachings of the prior art. Kalenboeck et al anticipate the claimed method.

Status of Claims

17. No claims allowed.

Conclusion

18. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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July 21, 2006

NITA MINNIFIELD
PRIMARY EXAMINER